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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,644	01/08/2002	Jacques F. Banchereau	AGT.10006NP	7691

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EXAMINER	
CHANDRA, GYAN	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
03/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/042,644	BANCHEREAU ET AL.	
	Examiner	Art Unit	
	GYAN CHANDRA	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52,69-77,80-82,84-92 and 96-102* is/are pending in the application.

4a) Of the above claim(s) *1-52,69-77,82,84,101 and 102* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *80,81,85-92 and 96-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/07,12/27/07 and 1/17/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on 12/27/2007 is acknowledged and fully considered.

Status of Application, Amendments, And/Or Claims

The addition of new claims 100-102 has been made of record.

Claims 1-52, 69-77, 80-82, 84-92 and 96-102 are pending.

Claims 1-52, 69-77, 82 and 84 remain withdrawn and claims 101-102 are withdrawn for reciting a non-elected invention.

Claims 80-81, 85-92 and 96-100 are examined on the merit to the extent that they read on the elected species psoriasis, and an antibody as the interferon antagonist.

Information Disclosure Statement

The Information Disclosure Statements submitted on 10/18/07, 12/27/07 and 1/17/08 have been considered.

Claim Objections

Claims 81 and 100 are objected for reciting non-elected inventions (i.e., aplastic anemia, Behecet's disease.... and lupus).

It is noted that the objection of claim 81 for reciting non elected inventions was withdrawn by mistake in the office action mailed on 12/14/2006.

Response to Arguments

Claim Rejections - 35 USC § 102-*maintained*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 80-81, 85-92 and 96-99 remain rejected and newly added claim 100 is rejected under 35 U.S.C. 102(b) as being anticipated by Skurkovich et al (US Patent No. 5,888,511) for the reasons of record in the previous Office Action mailed on 7/27/2007 and discussed below.

Claims 80-81, 85-92 and 96-100 are broadly drawn to a method of treating an autoimmune disease in a subject comprising administering a composition consisting of one or more antibodies consisting of one or more humanized or human monoclonal anti-IFN-α antibodies or antigen-binding fragments thereof and a diluent, a preservative, a solubilizer, an emulsifier, an adjuvant, a carrier, a buffer, a pharmaceutical additive, a detergent, an anti-oxidant, a bulking substance, a tonicity modifier, a flavoring agent, a lubricant, a suspending agent, a filler, a glidant, a compression aid, a binder, a tablet-disintegrating agent, an encapsulating material, a sweetener, a thickening agent, a color, a viscosity regulator, a stabilizer, an osmo-regulator, a pharmaceutically acceptable propellant, a flavorant, a dye, a coating, or a combination of any thereof, wherein said autoimmune disease is not rheumatoid arthritis, Acquired Immune Deficiency Syndrome (AIDS), or diabetes, and wherein no neutralizing anti-TNF antibodies are used in the method, wherein one or more anti- IFN-α antibodies or antigen binding fragment are administered at a dosage of about 1 to about 10 fold molar excess of interferon, wherein one or more anti- IFN-α antibodies or antigen binding fragments thereof reduce binding of a type I interferon to its receptor, wherein one or more anti- IFN-α antibodies or antigen binding fragments thereof reduce interferon-

dependent signal transduction, wherein one or more anti- IFN-α antibodies or antigen binding fragments thereof reduce interferon serum levels, wherein one or more anti-IFN-α antibodies or antigen binding fragments thereof reduce interferon secretion from cell as measured by interferon receptor binding assay, wherein one or more anti- IFN-α antibodies or antigen binding fragments thereof reduce bioavailability of interferon in serum as measured by an interferon receptor binding assay, wherein one or more anti-IFN-α antibodies or antigen binding fragments thereof reduce development of cells which produce type I interferon in the subject as measured by a monocyte differentiation assay, and wherein the autoimmune diseases is psoriasis.

Applicants argue (page 12 of Response) that the reference Skurkovich et al does not teach effective treatment methods comprising administering a composition consisting of humanized or human monoclonal antibodies against IFN alpha where no neutralizing anti-TNF antibodies are used. Applicants argue that claim 99 is drawn to a method of treating an autoimmune disease “consisting of” administering of administering a composition consisting of humanized or human monoclonal antibodies against IFN-α and one or more of other recited components. Applicants argue (page 13 of Response) that although Skurkovich et al teach that each autoimmune disease comprises overproduction of IFN-α, they emphasize in the previous sentence that autoimmune diseases comprise complex pathological agents which must be removed, neutralized or inhibited. Applicants argue (page 14) that the teachings of Skurkovich et al comprises an effective amount of one or more anti-IFN-α in addition to utilization of

extracorporeal treatment. Further, Applicants argue that the teachings of Skurkovich et al are only specific for RA and AIDS wherein alleged treatments use antibodies against IFN-α as the sole active agent (RA and AIDS).

Applicants' arguments have been fully considered but they are not persuasive because claims 80-81, 85-92 and 96-98 are drawn to a method treating an autoimmune disease "comprising" administering a composition consisting of humanized or human monoclonal antibodies against IFN alpha which does not exclude the additional method (extracorporeal treatment) taught by Skurkovich et al. However, Skurkovich et al teach administering anti-IFN alpha antibody to treat patients having Ankylosing Spondylitis, which clearly meets the limitation of claim 80 (Example 3, group B). Applicants' arguments regarding claim 99 that the claim is drawn to a method of treating an autoimmune disease "consisting of" administering a composition "consisting of" and Applicants' arguments that Skurkovich et al do not teach any other disease except RA and AIDS where they use antibodies against IFN-α as the sole active agent have been fully considered but they are not persuasive because Skurkovich et al teach treating an autoimmune disease "Ankylosing Spondylitis" by administering an anti-IFN-α (see Example 3 and Table 2). Applicants' argument that Skurkovich et al (column 6, lines 16+) teach treating an autoimmune disease by administering an anti-IFN-α which is in addition to extracorporeal treatment is persuasive, however, Skurkovich et al also teach treating autoimmune diseases by an anti-IFN-α (Example 3) where no extracorporeal treatment is involved which meets the limitations of instantly claimed invention (including claim 99). Skurkovich et al teach using suitable carriers or excipients which

are well known in the art (column 19, lines 3+). They teach that an excipient could be starch or lactose (column 19, line 32). Further, Skurkovich et al teach using flavoring agents, glidant, adjuvants or sweetening agents in a pharmaceutical composition (column 19, lines 31+). Therefore, the rejection is maintained.

Conclusion

No Claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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19 February 2008
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/Robert Landsman/
Primary Examiner, Art Unit 1647